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Date of Signature

Case No. 8627-368

Client Ref. No. PA-5469-RFB

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Darin G. Schaeffer et al.

Serial No.: 10/756,851

Filing Date: January 14, 2004

For: INTRODUCER

Examiner: Timothy J. Neal

Group Art Unit No.: 3731

### DECLARATION UNDER 37 C.F.R. § 1.132

Commissioner for Patents

Washington, D.C. 20231

Dear Sir:

Now comes Darin G. Schaeffer, an inventor of the above-identified patent application, who declares and states:

1. I am currently employed by Cook Incorporated ("Cook") as an engineer. I have held this position with Cook since before January 14, 2004, when the present application was filed. My principal job responsibility involves designing stents, catheters

and related devices and methods related thereto. I have personal knowledge of the following facts set forth below.

2. I have reviewed the Office Action dated January 9, 2007, in the above-identified patent application. My understanding is that the application has been rejected based on Stephens (U.S. Patent No. 6,224,586) and Figures 1-8 of the present application. I have reviewed the Stephens patent and Figures 1-8 of the application in an effort to understand the Examiner's rejection of the claims in the present application.

3. The invention of my application relates to an introducer for medical devices, such as stented balloons. The introducer is a special instrument specifically designed to introduce medical devices through a hemostatic valve. The hemostatic valve described in the application is a specific type of valve that has a soft valve member and an opening extending through the valve member. The soft valve member is designed to collapse the valve opening so that the valve opening spontaneously closes when there is no device inserted through the hemostatic valve. In order to insert a device through the hemostatic valve, the device must be forced through the valve opening in the valve member. This causes the soft valve member to compress or flex sufficiently for the valve opening to expand to receive the device that is being inserted through the hemostatic valve. As the device is inserted through the hemostatic valve, the valve member presses against the surfaces of the device to prevent blood from leaking through the valve opening.

4. It is clear from the disclosure of the Stephens patent that the position guide 100 is not an introducer used to introduce medical devices through a valve. The Stephens position guide 100 is designed to maintain a fixed distance between the Tuohy-Borst connector 308 and the pullback device 310. The position guide 100 is specifically designed to be used with the pullback device 310 to allow precise pullback of a catheter 202. In particular, the pullback device 310 engages the hubs 106, 108 of the position guide 100 and pulls on the catheter 202 with rollers. The Stephens patent also clearly sets forth that the position guide 100 is not used as an introducer because the position guide 100 is pressed onto the catheter 202 by pressing the catheter 202 through the open channel 104. Furthermore, Figure 3 shows the position guide 100 being loaded onto the catheter 202 after the catheter 202 has been inserted through a

Tuohy-Borst connector 308. By contrast, an introducer is inserted through the hemostatic valve first. The medical device is then pushed through the lumen of the introducer until it passes through the valve opening of the hemostatic valve. The introducer may be pre-loaded over the distal end of the medical device before insertion through the hemostatic valve.

5. Furthermore, the Tuohy-Borst connector 308 that is described in the Stephens patent is not the hemostatic valve described in my application. A Tuohy-Borst connector is a manually actuated connector that can be opened and closed by twisting the connector or by other manually actuated means. In other words, the user of the Tuohy-Borst connector can manually select whether the connector is open or closed, irrespective of whether a device is inserted through the connector. Typically, a Tuohy-Borst connector is operated by first manually opening the connector. A device is then inserted through the connector while it is open. The Tuohy-Borst connector is then manually closed to seal the connector against the inserted device. By contrast, the hemostatic valve of my application cannot be manually opened and closed by actuating the valve. Instead, the valve is naturally closed, and there is no actuation mechanism for opening the valve.

6. In my opinion, it would not have been obvious to modify the Stephens position guide 100 to achieve the claimed invention. In particular, the Stephens position guide 100 is not an introducer. Thus, there would have been no motivation to add a flanged proximal end to the position guide 100. Furthermore, the Stephens position guide 100 is not forced through a hemostatic valve as described in my application. Instead, the Stephens position guide 100 is used with a Tuohy-Borst connector 308 which is manually actuated to open the connector 308. Thus, there would have been no motivation to add a beveled distal end to the position guide 100.

7. It is also my opinion that there would have been no motivation to modify Figures 1-8 of the application to add a longitudinal slot to a flexible plastic sheath with a beveled distal end or a flanged proximal end. As explained above, an introducer must be designed to force open the valve member of a hemostatic valve. This requires substantial column and circumferential strength to overcome the pressure imposed by the valve member. The Stephens position guide 100 did not confront this problem

because the Stephens patent discloses using a Tuohy-Borst connector 308 and not the hemostatic valve of the application. Indeed, Figures 1-8 of the present application teach away from adding a longitudinal slot to a flexible plastic sheath for an introducer because the only prior art introducer with a slot was made from rigid metal. Thus, the prior art appears to teach that full-round plastic (without a slot) or rigid metal (with or without a slot) was the material of choice for introducers so that the column pressure and circumferential pressure of the hemostatic valve could be overcome while maintaining a cross-section to pass the medical device through it.

8. I state that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with knowledge that willful false statements are the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

Respectfully submitted,

 May 3<sup>rd</sup>, 2007  
Darin G. Schaeffer